

IN THE CLAIMS:

1. (Twice Amended) A method for detecting the presence of squalene antibodies capable of specific binding with squalene, comprising:

providing a solid support suitable for allowing specific binding of squalene with squalene antibodies;

immobilizing squalene on the solid support;

washing the immobilized squalene with blocking agent;

contacting the immobilized squalene with a test sample containing monoclonal squalene antibodies or fragments thereof capable of specific binding with squalene;

allowing the squalene antibodies to specifically bind to the immobilized squalene to form a specific antibody complex ~~with little or no cross reactivity~~;

contacting the antibody complex with a ligand that specifically binds to the complex;

contacting the ligand with an indicator agent; and

detecting the indicator agent.

2. (Previously Amended) The method of claim 1 wherein the solid support is elected from the group of solid supports consisting of polystyrene and polyvinylidene fluoride.

3. (Original) The method of claim 1 wherein the blocking agent is a blocking agent that reduces background interference with antibody binding the immobilized squalene.

4. (Original) The method of claim 3 wherein the blocking agent is selected from the group of blocking agents consisting of phosphate buffered saline, bovine serum albumin, gelatin, casein, or mixtures thereof.

5. (Original) The method of claim 4 wherein the amount of bovine serum albumin is up to about 5%.

6. (Original) The method of claim 5 wherein the amount of bovine serum albumin is between about 1% and about 2%.

7. (Original) The method of claim 1 wherein the blocking agent is free of fetal bovine serum.

8. (Original) The method of claim 1 wherein the test sample comprises serum.

9. (Original) The method of claim 1 wherein the test sample comprises human serum or mouse serum.

10. (Amended) The method of claim 1 wherein the ligand is a monoclonal antibody exhibiting strong dose-dependent binding or a fragment thereof.

11. (Original) The method of claim 1 wherein the indicator agent is selected from the group consisting of an enzyme; a protein; a fluorochrome; a fluorescent protein; a radioisotope; and a nucleic acid segment.

12. (Original) The method of claim 11 wherein the indicator agent is peroxidase.

13. (Withdrawn) A method for detecting the presence of squalene antibodies comprising using an ELISA protocol for detecting the presence of squalene antibodies in serum, wherein said protocol comprises using bovine serum albumin as a diluent or blocking agent.

14. (Withdrawn) The method of claim 14 wherein the method further comprises using a monoclonal antibody to specifically bind to any squalene antibodies present in the serum.

15. (Original) The method of claim 1 wherein immobilizing squalene on a solid support comprises contacting the solid support with a composition comprising squalene.

16. (Original) The method of claim 15 the composition comprises liposomes containing squalene.

17. (Cancelled herein)

18. (Cancelled previously)

19. (Withdrawn) A method of validating an assay for the detection of squalene antibodies in serum comprising an ELISA assay in which the ligand is an antibody produced in an immunological response to a squalene antigen.

20. (Amended) An assay for detecting antibody induced by injection of squalene comprising

providing a solid support suitable for use with squalene antibodies;

immobilizing squalene on the solid support;

washing the immobilized squalene with blocking agent;

contacting the immobilized squalene with a test sample containing monoclonal squalene antibodies or fragments thereof;

allowing the monoclonal squalene antibodies to bind to the immobilized squalene to form an antibody complex;

contacting the antibody complex with a ligand that specifically binds to the complex;

contacting the ligand with an indicator agent; and

detecting the indicator agent.

21. (Original) The method of claim ~~20~~ wherein the assay is validated using as a positive control an antibody known to react with squalene.